

tool and extrapolated into N/V levels as: grade A (none to mild nausea; no emesis recorded), grade B (moderate nausea; no emesis recorded), or grade C (moderate nausea for more than half the time, or any severe nausea or any emesis). Lorazepam and dolasetron were used prophylactically from beginning of chemotherapy through day +1. Oral prochlorperazine was given prn. **Results:** 23 of 29 of patients experienced Grade A N/V during conditioning-reinfusion phase. All patients received anti-emetic irrespective of N/V grade. During Day +1 to Day +10, 13 of 29 patients experienced no higher than Grade A N/V, with 8 of those 13 requiring anti-emetics. During Day +11 to Day +14, 19 of 29 had Grade A N/V with 3 of those 19 requiring anti-emetics. A higher percentage (50%) of melphalan patients experienced Grade C N/V than with BEAC (16%) or CBV (20%) in the third phase. 1 melphalan patient and 1 BEAC patient required dronabinol to control persistent N/V. **Conclusions:** Melphalan appears to cause more severe and more delayed/extended N/V than BEAC or CBV. Patients receiving melphalan appeared significantly less likely to progress through PBSCT without receiving any anti-emetics. While more patients are required to strengthen statistical significance, we believe these findings are predictive of N/V associated with these three conditioning regimens. Further study should ascertain improved approaches to N/V assessment and management.

Table. Patients Experiencing N/V by Grade by PBSCT Phase

Patients Grouped by Grade N/V per PBSCT Phase				
Conditioning Regimen	Level of N/V	Conditioning-Reinfusion	Day +1	Day +11
		Day -7 to Day 0 (% of Patients)	through Day +10 (% of Patients)	through Day +14 (% of Patients)
Melphalan (n = 12)	Grade C	3 (25%)	6 (50%)	6 (50%)
	Grade B	0 (0%)	2 (16%)	0 (0%)
	Grade A	9 (75%)	4 (33%)	6 (50%)
BEAC (n = 12)	Grade C	1 (8%)	4 (33%)	2 (16%)
	Grade B	0 (0%)	2 (16%)	0 (0%)
	Grade A	11 (92%)	6 (50%)	10 (84%)
CBV (n = 5)	Grade C	2 (40%)	2 (40%)	1 (20%)
	Grade B	0 (0%)	0 (0%)	1 (20%)
	Grade A	3 (60%)	3 (60%)	3 (60%)

250

A RETROSPECTIVE ANALYSIS OF HOSPITAL ADMISSIONS IN AN OUTPATIENT STEM CELL TRANSPLANT FACILITY

Malone, C., Paivanas, N., Spiros, A.R., Spira, A.I., Orloff, G.J., Beveridge, R.A. Fairfax Stem Cell Transplant Program INOVA Fairfax Hospital Cancer Center, Fairfax, VA

Methods: A retrospective chart review was conducted on 49 patients receiving autologous stem cell transplants in the outpatient setting within a three year time frame. The patients were transplanted for multiple myeloma (MM), Hodgkin's lymphoma (HD), or Non-Hodgkin's lymphoma (NHL). The analysis considered: age at transplant, past medical history, disease status at transplant, and outcomes of pretesting, to determine what characteristics might predispose for hospital admission. **Results:** Thirteen patients were admitted from the outpatient setting, 8 for sepsis/neutropenic fever, 3 for dehydration or vomiting, 1 for mental status changes, and one for cardiac failure. Of the 13 (thirteen) patients requiring hospital admission, 12 had a disease status at time of transplant of partial remission (PR), 1 (with 3 prior relapses) was in complete remission (CR) prior to PBSCT. One patient was admitted after white blood cell engraftment and one admitted during chemotherapy administration. Of the patients not requiring hospital admission from the outpatient setting, 14 were PR, 16 were CR, 5 were relapsed with chemosensitive disease, and 1 was Rel1 (first relapse after a CR). In the chart review, no statistical correlations were found between the admitted and non-admitted groups for: age, past medical history, and pretest indica-

tors. **Conclusions:** Patients with MM had a higher rate of hospital admission from the outpatient setting versus those with either HD or NHL. The incidence of hospitalization seems to be especially prevalent in patients whose disease processes were not in complete remission. This analysis suggests a correlation of disease and pre-transplant status as a predictor of hospital admission; however, further study is indicated.

Table. Frequency of Hospitalization Among Disorders

Disease	Patients Admitted	Patients Not Admitted
MM (n = 20)	9 (45.0%)	11 (55.0%)
HD (n = 9)	2 (22.2%)	7 (77.8%)
NHL (n = 20)	2 (10.0%)	18 (90.0%)

251

SAFETY AND TOLERABILITY OF COMBINATION ANIDULAFUNGIN (ANID) AND LIPOSOMAL AMPHOTERICIN B (LAMB) FOR THE TREATMENT OF INVASIVE ASPERGILLOSIS (IA)

Herbrecht, R.¹, Grabam, D.², Schuster, M.³, Henkel, T.⁴, Krause, D.⁴, Schranz, J.⁴, Garbino, J.⁵, Caillot, D.⁶, Reinhardt, J.⁷, Maertens, J.⁸ 1. Département d'Hématologie et d'Oncologie, Hôpital de Haute-pierre, Strasbourg, France; 2. Springfield Clinic Research, Springfield, IL; 3. University of Pennsylvania, Infectious Disease Division, Philadelphia, PA; 4. Vicuron Pharmaceuticals, King of Prussia, PA; 5. Geneva University Hospital, Infectious Diseases, Switzerland; 6. Haematologie Clinique, Hôpital Bocage, CHU Dijon, France; 7. Christiana Care Health Services, Infectious Disease Clinical Studies Research Institute, Newark; 8. University Hospital, Herestraat 49, Department Pathophysiology, Leuven, Belgium

Background: Response rates with existing monotherapy for IA remain suboptimal, and mortality remains unacceptably high. Anidulafungin is a novel echinocandin (EC) in late stage development with potent *in vitro* activity that is additive or synergistic with amphotericin B (AmB) against *Aspergillus* spp. ANID's distinct PK characteristics and favorable safety profile support development as a first-line therapeutic agent. AmB has efficacy for IA but has unacceptable toxicity. Combination of ANID and LAmB may offer improved outcome with no excessive toxicity. The safety of combination ANID plus LAmB was evaluated. **Methods:** Pts \geq 18 yrs with proven or probable IA (per EORTC, MSG criteria) and life expectancy $>$ 72 hrs were enrolled into an open-label, non-comparative study. Exclusion criteria included receipt of more than 5 days of antifungal therapy (unless treatment failure) and AST/ALT $>$ 5 X ULN. ANID was given as 200 mg IV loading dose day 1 with 100 mg daily maintenance (200/100mg); LAmB was given daily up to 5 mg/kg/day. Treatment continued until resolution of signs/symptoms up to 90 days. Clinical assessments were done on therapy, end of therapy (EOT) and at 4 weeks post EOT (FU). Safety labs and ECGs were performed. **Results:** Data on 17 of 30 enrolled patients are presented. Mean age was 55 (range 21-79). The majority of pts had pulmonary IA (12); other sites included CNS (2), cutaneous, hepatic and bone (1 each). Risk factors for IA were steroid use (3); AML (3); ALL (1); other malignancies (2); aplastic anemia (1) and other malignancies (2); allogeneic BMT (3); heart (1) or liver transplant (1). 12 of 17 patients had at least 1 drug-related adverse event (DRAE). Of these pts, 7 and 3 had an AE expected with LAmB and with LAmB and/or ANID, respectively. DRAEs reported in \geq 2 pts were hypokalemia, increased transaminases, increased ALP, hypomagnesemia and flushing. 14 pts had a total of 22 serious AEs; only 2 were drug related (renal failure, an expected event for LAmB; abnormal LFTs). There were 9 deaths during the 90 day study period; none considered related to study drug. No trends attributable to ANID/LAmB were seen for post-baseline hematology or chemistry results. **Conclusions:** The patterns of AEs and laboratory abnormalities were not unexpected for this ill population. No untoward safety findings were found. Based upon available data, ANID and LAmB can be safely co-administered.